Mylan's Responses to Arguments Raised in Plaintiffs' May 11, 2020 Letter

No.	Plaintiffs' Argument	Mylan's Response
Standalone Search Terms		
1	Mylan improperly removed **DMF**.	Mylan does not use the solvent dimethylformamide, or "DMF", in the manufacture of valsartan, therefore this term is inappropriate as to Mylan and could not result in the capture of responsive documents.
2	Mylan has not performed any due diligence to determine whether **DMF** hits were not responsive, nor did they propose any modifiers or alternatives.	Because "DMF" is a common abbreviation for the term "Drug Master File", it is causing numerous false positives related to other drugs, particularly when run as a standalone term. Moreover, there is no justifiable reason to run "DMF" as a primary term because Mylan has already produced the Drug Master File.
3	Mylan quietly removed a host of agreed upon numbers that are used to refer to Valsartan.	The "agreed upon numbers" that Mylan removed are the ANDA and/or DMF numbers related to valsartan manufactured by other defendants. These numbers, run as standalone terms, were causing false hits not related to valsartan.
4	Mylan improperly restricted searches for **Establishment Inspection Reports** to drug names when reports apply to facilities and not the drug names and the list of facilities is incomplete.	Mylan has already produced and/or will produce all Establishment Inspection Reports and formal FDA correspondence during the relevant time period pertaining to the 5 Mylan manufacturing facilities at issue in this litigation. In order to prevent an overbroad collection of documents, most of which were already produced, Mylan proposed limited the primary term "Establishment Inspection Reports" to the drugs at issue in this litigation.

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5	Mylan improperly restricted searches for **483 letters** and other FDA actions to drug names and facility names; already have low counts for OIA and VAIs.	Mylan has already produced and/or will produce all Establishment Inspection Reports and formal FDA correspondence during the relevant time period pertaining to the 5 Mylan manufacturing facilities at issue in this litigation. Facilities that did not manufacture valsartan for market or sale in the United States during the relevant time period are no relevance to this litigation, and therefore formal FDA correspondence related to these facilities cannot be responsive. Further, the term "VAI" is used also in the Regulatory terms.
6	Mylan improperly restricted **genotoxic*** and **carcin*** to drug name or solvent.	In light of the high hit counts, these terms should not be Standalone Terms. Mylan added reasonable modifiers (drug names and solvent names) given that this litigation involves the alleged contamination of valsartan MPI based on the use of recovered solvent.
Drug Modifier Terms		
7	Mylan improperly removed **HCT** and **HCTZ** from the list of drug names.	These are common abbreviations that relate to numerous drugs in Mylan's portfolio other than valsartan. As a result, these drug name modifiers, when run with primary terms, were leading to the capture of non-responsive documents.
Regulatory Terms		
8	Proposed modifiers for **inspect*** and **investigat*** would not capture inspections of the solvents, inspections by regulatory agencies, and facility inspections.	As originally conceived, these primary terms were generating unacceptably large hit counts, and Mylan's document sampling confirmed a high rate of non-responsiveness. If Plaintiffs had agreed to meet-and-confer with Mylan in good faith when Mylan submitted the Revised Search Terms in March 2020, Plaintiffs could have raised this issue and Mylan

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		would have considered adding additional modifiers to address these gaps.
9	Mylan improperly added a facility modifier to **observation***	Absent a facility modifier, the term "observation" if far too broad, as evidenced by the high volume of hit counts being captured. The facility modifier, which would serve the purpose of capturing documents where "observations" were made at one of the sites where the valsartan at issue was manufactured, increase the likelihood that responsive documents will be captured.
10	Mylan improperly removed **warn***	The term "warn" is far too broad, as evidenced by the high volume of hit counts being captured. Further, Mylan has already produced, or will produce, all formal FDA correspondence related to warning letters sent by FDA to the 5 manufacturing facilities where valsartan that was marketed and sold in the United States was manufactured. Further, if Plaintiffs had agreed to meet-and-confer with Mylan in good faith when Mylan submitted the Revised Search Terms in March 2020, Plaintiffs could have raised this issue and Mylan would have considered adding additional modifiers to address any gaps caused by eliminating this term.
11	Removal of **(master /3 files) or Establishment pre/3 Inspection** cannot be based on volume of hits because hits are relatively lower than other terms.	Just because a term or term is capturing a "lower" volume of hits counts does not mean that the term should not be refined or removed. Mylan has already produced the Drug Master File related to valsartan. Likewise, Mylan has or will provide formal FDA correspondence related to the 5 manufacturing facilities where valsartan that was marketed and sold in the United States was

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		manufactured. Nevertheless, if Plaintiffs had agreed to meet-and-confer with Mylan in good faith when Mylan submitted the Revised Search Terms in March 2020, Plaintiffs could have raised this issue and Mylan would have considered adding additional modifiers to address any gaps caused by eliminating these terms.
12	**CAPA or corrective pre/3 "preventative action"** was moved to QA-Testing tab, which improperly eliminates hits where drug or solvent are not mentioned but facility or regulatory agency are referenced.	If Plaintiffs had agreed to meet-and-confer with Mylan in good faith when Mylan submitted the Revised Search Terms in March 2020, Plaintiffs could have raised this issue and Mylan would have considered adding additional modifiers to address any gaps caused by eliminating these terms.
cGMP (current Good Manufacturing Practice) Terms		
13	Mylan raised legitimate concerns but did not adopt Plaintiffs' suggestion to construct a more tailored search to avoid email footer language.	Plaintiffs are incorrect. Mylan did add **destroy* NOT "immediately destroy all electronic"** to the revised terms list. The cumulative hit count numbers provided by Mylan accounted for this.
14	Mylan should apply proximity of /300 wherever /50 is proposed because an average paragraph is 100-200 words.	A proximity limiter of 300 is high compared to typical search term proximity modifiers. Mylan's /50 proximity limiter is more than adequate to capture responsive documents.
QA-Testing Terms		
15	Mylan improperly applied a proximity modifier of /50 to almost all of the terms, such that they must appear within a quarter paragraph of the drug/solvent/aberran*/etc.	See No. 14 above.
16	Mylan improperly removed key terms such as **observation**, **fail***, **problem** and **quality** without any attempt to modify or refine them. But Mylan kept **detect*** without modifiers.	These are not "key terms." Rather, they are a glossary of generic words which are highly common in the communications and documents of a global pharmaceutical company. Not surprisingly, these terms were leading to some of the largest hit counts of any

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		primary terms. Plaintiffs' insistence that these words be included as search terms – and without proximity limiters – is untethered from reality. For examples, just because the word "quality" appears somewhere in a document that also contains the word "valsartan" does not mean it has any relevance to this litigation.
Manufacturing Terms		
17	**recycl*** was limited to w/2 **solvent**, reducing volume by 99.9%.	Since ***NDMA*** is already a term and **solvent*** is paired with cancer terms, **recycl* as a primary terms adds little** value. Further, Mylan determined that an anomaly contained in calendar invitations was causing **recycl** * to generate false positives. The lowered hit count reflects this.
18	Mylan improperly removed **error*** without explanation or justification.	"Error" is a highly common word and therefore an overly broad term used by itself and not necessarily related to this litigation. If a certain error type was noted, it could possibly be combined with additional terms, but Plaintiffs' version of the search terms does not contemplate this.
19	Mylan improperly removed **expir*** without explanation or justification.	"expir*, which is expanded to include "expiration" by the wildcard is a highly common word in the pharmaceutical industry, and therefore an overly broad term used by itself.
20	Mylan improperly removed **solvent*** without explanation or justification.	Plaintiffs are incorrect. Mylan did not remove this term wholesale. It is included on the standalone term list and with other modifiers.
21	Limiting the proximity search to 50 words is wholly inappropriate, particularly when applied to in such a blanket manner.	Plaintiffs are incorrect for 4 reasons. • First, the subject of the email would be included as part of the extracted search.

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		• Second, the name of the attachment would be available to the proximity search. • Third, folder names are not typically indexed by default, but this is configurable and can be added to most search indices. • Fourth, metadata such as the file name is typically not indexed but is also configurable in most major search engines.
Medical Conditions Terms		
22	Eliminating **blood*** and adding the **/50** proximity restriction reduced 86% of the terms.	Based on Mylan's sampling, 0% of the documents reviewed for this term were responsive. Thus, broad reduction does not mean that responsive document are eliminated.
Entities Terms		
23	Plaintiffs do not concur on the wholesale removal of **distribut*** which references Distributors generically.	This term is too broad, and the rationale given by Plaintiff's regarding its value is insufficient.
24	Defendants improperly removed **Mylan**	Plaintiffs accept removal from of "Mylan" from Mylan's searches. The parties never contemplated that Mylan would be required to run its own entity names against its custodians.
25	Mylan improperly removed **Matrix**	Plaintiffs accept removal from Matrix from Mylan's searches. The parties never contemplated that Mylan would be required to run its own entity names against its custodians.
Solvent Modifiers		
26	Mylan improperly removed **acid** from the solvent modifiers.	"acid" is a poor modifier term because it is far to general and common in the pharmaceutical industry. Mylan's testing has indicated that **acid** leads to a vast expansion of hits, although there is no indication that they would necessarily be related to valsartan or to this litigation.

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Medical Condition Modifiers		
27	Mylan improperly removed **AER**	"AER", which is a abbreviation for "adverse event report" is far to general and common in the pharmaceutical industry. Only adverse event reports related to valsartan could be responsive, therefore this is a poor modifier term applied more broadly as Plaintiffs propose.
28	Mylan improperly removed **adverse event***	"adverse event" is far to general and common in the pharmaceutical industry. Only adverse event reports related to valsartan could be responsive, therefore this is a poor modifier term applied more broadly as Plaintiffs propose.
29	Mylan improperly removed **blood***, reversing Defendants' previous position that it should be combined with other terms such as **carcin***, **cancer*** and **liver***.	Valsartan is a blood pressure mediation. Plaintiffs have subsequently asserted that there is a blood test that can detect nitrosamines, however, Mylan is not aware of any such test. Further, based on Mylan's sampling, 0% of the documents reviewed for the primary term **blood** term were responsive. Thus, Mylan has no reason to believe that blood would be any more effective as a modifier term with regard to the capture of responsive documents.
Facilities Names Modifiers		
30	Mylan only includes the FEI numbers and not the names. Plaintiffs insist that at the very least Unit 3, Unit 8, Aurangabad, Nashik and Morgantown must be included.	If Plaintiffs had agreed to meet-and-confer with Mylan in good faith when Mylan submitted the Revised Search Terms in March 2020, Plaintiffs could have raised this issue and Mylan would have considered adding some or all of the facility locations as modifiers, as Plaintiffs suggest.
Sampling		
31	Mylan's sample set did not include a "statistically significant" number of documents, and is therefore inherently unreliable.	Mylan performed a follow-up sample set review using the methodology suggested by Plaintiffs. The results of Mylan's sample set review of this

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		"statistically significant" number of documents mirrored its initial sample review. Ninety-four percent (94%) of the documents were non-responsive.